

NOV 25 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Thomas T. Andersen *et al.*
APPLICATION NO: 09/872,623 EXAMINER: Sheela Jitendra Huff
FILING DATE: June 2, 2001 ART UNIT: 1642
FOR: *ALPHA-FETOPROTEIN PEPTIDES AND USES THEREOF*

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DR. THOMAS ANDERSEN UNDER 37 C.F.R. §1.132

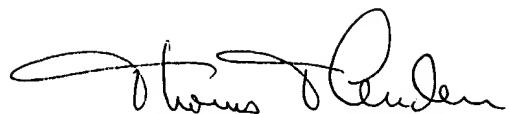
I, THOMAS ANDERSEN, of 15 Catalpa Drive, Albany, NY 12209, declare and state that:

1. I am a co-inventor, together with James Bennett, Herbert Jacobson, and Fassil Mesfin, in the above-referenced patent application.
2. I received a Ph.D. from the University of Kansas in 1978, and received post-doctoral training at Duke University.
3. I am currently employed by Albany Medical College ("AMC") as an Assistant Dean and teaching professor. The Assignee to this invention, CLF Medical Technology Acceleration Program, Inc., is the licensing arm for AMC. A principal aspect of my role at AMC has been studying and elucidating alpha-fetoprotein ("AFP") because this fetal protein, when incubated with estrogen, acquires the ability to prevent the growth of estrogen-dependent breast cancers. This protein is the subject matter of the present invention.
4. I have reviewed, and understand, the above-referenced application, and its updated claims as amended in the Response to be filed concurrently herewith. I have also reviewed the Office Action dated August 25, 2003. I understand that claims 1-3 and 5 stand rejected under 35 U.S.C. § 102(a) as anticipated by Mesfin *et al.* (2001), a paper written by the joint

inventors of the instant application (hereinafter "Mesfin"). Mesfin discloses sequences within the scope of claims 1-3 and 5, namely EMTOVNOG and EMTOVNOGQ.

5. I now submit, on behalf of all the inventors, evidence indicating conception and reduction to practice of the peptides disclosed by Mesfin, prior to the March 2001 publication date of Mesfin. This evidence regarding EMTOVNOG (SEQ ID NO:4) and EMTOVNOGQ (SEQ ID NO:5) is attached hereto as Exhibit A.
6. Presented in Exhibit A are six (6) pages which are true copies from Applicants' notebooks leading to the invention of the instant application. These pages show the synthesis and bioassay of SEQ ID NO:5 (EMTOVNOGQ) on June 3-4, 2000, and June 8-9, 2000, respectively. As denoted in our lab notebooks, the name of the peptide is 9merHyPro. This is shorthand for a peptide of 9 amino acids wherein the proline (P) residues were both substituted by Hydroxyproline (O). Although the sequence on the first sheet indicates Pro in positions 4 and 7, the synthesizer computer uses the Pro code by default. The synthesizer was not re-programmed to print HyPro in place of Pro.
7. Page 2 of Exhibit A is dated June 8, 2000 and represents the concentrations of the peptide to be tested in the Uterine Growth Assay as disclosed in the instant application. The remaining pages of Exhibit A, dated June 9, 2000, detail the findings of the assay.
8. Thus, peptides disclosed by Mesfin (EMTOVNOG (SEQ ID NO:4) and EMTOVNOGQ (SEQ ID NO:5)) are documented to be in our possession well before the March 2001 publication date of Mesfin. Accordingly, Mesfin cannot anticipate claims 1-3 and claim 5, and the rejection should be withdrawn.
9. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.

Andersen, *et al.*
09/872,623


Thomas T. Andersen
Thomas T. Andersen, Ph.D.

Signed at Albany, NY

this 29 day of November, 2003

TRA 1855806v1

NOV-19-2003 WED 11:15 AM CLF PLW

FAX NO. 518 877 6546 6260 P. 03

NOV-19-03 WED 11:07 AM GRAD. STUDIES PROGRAM

FAX NO. 5182625183 P. 2

Notebook Name: 9merHyPro
Protocol Name: \Template
Chemistry Name: \OH Derivatives
Final Cycle: None off
Start time: 06/03/00, 02:09:11 PM
Finish time: 06/04/00, 01:38:41 AM
Status: Complete
Instrument name: Pioneer
Synthesis Position: 1
Sequence Name: 9merHyPro
Sequence: Glu - Met - Thr - Pro - Val - Asn - Pro - Gly - Gln -
Sequence length: 9
First AA Support: Off

Uterine Biosassay
6 - 8 - 00

I	Sal	Sal
II	Sal	E ₂
III	Fresh 9mer oN-hol 1mg made 6-4-00 Lyophil 6-6-00	E ₂
IV	" 10mg	E ₂
V	" 100 mg	E ₂
VI	" 1 ug	E ₂
VII	" 10 ug	E ₂
VIII	" 100 ug	E ₂

weigh out 700 ug diisobut in 3.5 ml. PBS 200 ug/ml ⁱⁿ 0.1

0.3 + 2.7 20 ug/ml
 " " 2 ug/ml
 " " 200 ug/ml
 " " 20 ug/ml
 " " 2 ug/ml

Neonatal Autopsy

10

Date 06-06-00

Treatment:	Birth Date	Age in days	Body wt. (grams)	Uterine wt. (mg)	UW/BW	X ± SD
I SAD. SAD.						
	1	7.94	4.9	0.612	0.83 ± 0.16	
	2	8.34	8.4 TB	1.602		
	3	8.30	6.9 TB	0.819		
	4	8.12	8.0	0.982		
	5	7.35	5.6 TB	0.762		
II SAD. E ₂						
	1	7.96	15.0 TB	1.674	1.04 ± 0.166	
	2	7.61	12.2	1.602		
	3	8.25	13.6 TB	1.645	$S_{UW} = 0.774$	
	4	8.35	14.9 TB	1.784		
	5	7.69	10.4	1.352		

1.412 / 0.834

Neonatal Autopsy

P2

Date 06-7-00

Treatment:

Birth Date Age in Days

Wt. (gms) Wt. (mg)

UW / BW
Pectoral
Extremes

X E S P

~~✓~~ Fresh Fetus E

Hy - Pro

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9.14

9.0

15

0.984

1.6

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Neonatal Autopsy

103

Date 06-9-00

Treatment:

Birth Date	Age in Days	Body wt. (gms)	Uterine wt. (mg)	Wt. / BW (X 10 ⁻³)
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II Fresh Pairr E₂

Hy - pro

100.29

1

8.76

12.6

7.8

13.9

1.43

1.43

1.43

1.43

1.43

1.43

1.43

Hy - pro

1

8.68

11.8

7.8

11.8

1.47

1.47

1.47

1.47

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1.47

1.47

II Fresh Pairr E₂

Hy - pro

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8.76

12.6

7.8

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Hy - pro

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Hy - pro

1612/0834

Neonatal Autopsy

Date 06-9-00

P4

Treatment:	Birth Date	Age in Days	Body wt.(grams)	Uterine wt. (mg)	UW/BW ratio	$\bar{X} \pm SD$
<u>W</u> Fresh Plac E2						
Myo-pro	1					
100 mg	2					
	3					
	4					
	5					
<u>W</u> Fresh Plac E2						
Myo-pro	1					
100 mg	2					
	3					
	4					
	5					